

MCRC Biobank Access Policy

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1. Access specifics

Applying to the Biobank

To access samples from the MCRC Biobank, a Biobank application must be submitted. Further details about the application process, ethics approval and how applications are reviewed are detailed in Section 2 of the Access Policy.

Existing Banked Samples

For the solid tumours, routine samples have been collected across a variety of tumour types from patients undergoing surgical resection as follows:

1. Frozen normal
2. Frozen tumour
3. Fixed normal (issued as sections only)
4. Fixed tumour (issued as sections only)
5. Blood (serum, plasma or whole blood)
6. Urine (includes urine cells for urology samples)

Samples of cryopreserved blood, bone marrow or leucopheresis product from patients with a range of blood disorders are also available.

Please enquire directly for further details about banked samples which may be available for use.

For rare or 'difficult to collect' cohorts, especially where significant clinical resource has been instrumental in establishing the collection, access will be granted on a collaborative basis only.

Biopsy or Pre-Treatment FFPE Samples

Should biopsy or pre-treatment FFPE samples be required (i.e. matched biopsy, primary tumour tissue or pre-treatment tissue), the Biobank can request matched FFPE samples from referring hospitals. Where this is the case, please consider the following:

- Any external block requests will be charged at a flat fee per patient, this is in addition to any other associated biobank [costs](#).
- Final numbers for any project of this type can only be confirmed once samples have been received at the Biobank for the following reasons:
 - The location of the primary biopsy sample is not always known
 - Available samples may not contain any residual tumour
 - The sample may have already been used for an alternative study or trial
- Projects requiring external block requests will significantly extend the lead time for sample acquisition for any project, both due to the administration required to request blocks and the turnaround times of local pathology departments.

Prospective Collection Studies

The MCRC Biobank accommodates prospective and tailored collections of tissue, blood and fluids for a variety of disease types. Collections from surgical patients can generally be organised directly through the Biobank, however any projects which require targeting specific non-surgical patient cohorts will often need clinical team support and facilitation.

Any prospective collections will require an approved Biobank application before they begin unless the following applies (reviewed on a case by case basis):

- The tumour type is rare and/or cohort numbers will be small and thus a collection needs to be established in the first instance
- There is funding available to support the prospective collection of samples or it is part of the Manchester Cancer Research Centre strategy
- Samples will remain stored in the Biobank until an application is approved for their use
- A Biobank Application is submitted within 12 months of the collection being established

The Biobank can collect and/or process a variety of additional sample types in line with existing Biobank SOPs.

Please note: the Biobank operational model is not able to support more advanced sample processing techniques such as blood PBMCs and cell culture. Should researchers require these sample types, fresh samples must be requested under an approved Biobank application.

For any prospective collection project, please contact the Biobank to determine:

- Whether your request can be accommodated within the current resource levels
- Whether there are any existing studies where prospective collection for your interested cohort may already be taking place

Where the Biobank have reached capacity (in either resource or with respect to sample availability), your project will be placed on a 'waiting list' and will begin once either resource becomes available or competing projects end.

Where different CRUK funded researchers are interested in the same sample types, every effort should be made to collaborate to maximise the availability of samples.

Timelines

Turnaround times for accessing Biobank samples may vary dependent on the complexity of the study and whether banked or prospective samples are being requested. If you have specific deadlines for your research project, please be clear about these in the application form or prior to the application process.

Charges

- The MCRC Biobank operates a cost recovery pricing model for services provided

- Biobank price lists are available on request, please confirm who is funding the work so the correct price list can be shared
- All Biobank applications will be charged an application fee of £100. A PO number should be supplied upon application
- Upon approval a set-up fee will be applied according to the relevant price list
- All amendments will be charged a combined application and set-up fee
- For most projects, fees will be charged on a per sample basis according to the price list. However, some projects may require a 'from scratch' costing to be developed. This will be communicated as part of the approval process
- For all new applications, a 'call-off' purchase order will be requested for the whole estimated study costs and must be provided before the project can begin
- Actual costs for all projects will be billed in retrospect each quarter

Tissue Microarrays and Archive Samples

The Biobank may accept applications from researchers wishing to access tissue microarrays (TMAs) and/or mine samples from the archive (pathology or existing research), however these types of projects will be judged on a project-by-project basis due to the additional resources these require. Researchers wishing to carry out these types of projects must approach the MCRC Biobank for initial discussions before applying.

For researchers who wish to commission the build of a TMA for unspecified future work, a TMA Build Application should be submitted.

All TMAs must be marked up by a qualified pathologist before the TMA build is conducted. Applicants should detail which pathologist they plan to collaborate with for their TMA build.

The cost of TMA projects will also be judged on a project-by-project basis, however there will be a flat rate hourly fee for the construction of the TMA costed in. The related sample acquisition cost for each TMA project will vary dependant on the number of cores per TMA and where the samples have come from (Biobank, pathology, research archive etc).

Please note: All TMA blocks constructed through the Biobank will remain in the MCRC Biobank as a resource for all Biobank applicants. Sections will be released for individual studies rather than the whole TMA block, however, where required, the TMA can be 'reserved' for that study until it has been completed.

Research Biopsies

Whilst most of the tissue samples that the Biobank collects will be collected during the course of an existing clinical procedure, the mechanism to collect additional research biopsies is being built into the Biobank consent model from <<insert date>>. Historically these types of studies required an additional project specific ethics application.

Please note that all patients will need to be assessed individually for their suitability for a research biopsy by the clinical care team and any other clinicians carrying out the procedure. Patients will also have the ability to decline any individual approach for a research biopsy regardless of their overarching consent to donate any research biopsies to the MCRC Biobank.

If you would like to consider requesting research biopsies to support your scientific question, please ensure your Biobank application includes:

- A clear rationale for requesting research biopsies and why your research question cannot be satisfied with samples that are collected during the course of routine care
- The name of a nominated individual within the clinical care team of each relevant disease area who will assess the patient's clinical suitability for a research biopsy
- An agreement in principle from the relevant service departments (e.g., surgery and pathology) that research biopsies can be supported
- Confirmation of funding arrangements for any additional procedures and reimbursement of expenses to patients for any additional expenses incurred

Data

Accompanying clinical information required with samples should be clearly requested on the application form. Baseline data available includes of the following:

- Demographic information (age & gender)
- Treatment history (as available)
- Diagnosis
- Family history (as available)
- Medical history (as available)
- Histopathological information (including stage/grade as available)
- Sample metadata

Where further information is required e.g. follow-up and survival data, this may be requested. However, please consider the following:

- Any follow-up data requires manual data collection from clinical systems and there will be a lead time and additional costs for any such requests
- The quality and completeness of the source data can vary significantly dependent on the hospital system from which is it accessed, the disease subtype and the age of the sample – the Biobank can only provide the data that is available
- It is common for patients to be treated locally for some part of their treatment and this information may not be available in the systems the Biobank can access

2. Applications for use of samples

Submitting an Application

Researchers wishing to use samples from the Biobank may first make an expression of interest to the MCRC Biobank.

To submit a formal research application, each researcher will need to write a full scientific proposal using the MCRC Biobank Project Application Form.

The Biobank will also accept applications for use of samples for QC and method development work. This allows access to samples for internal projects where initial data needs to be generated to inform future research work or provide a validation cohort for specific purposes e.g. for a piece of new technology. These types of projects do not allow for any research publications.

Please contact the Biobank for an electronic submission form for either type of application. Once the application form has been completed, it should be submitted to the MCRC Biobank via the 'SUBMIT BY EMAIL' function.

For researchers wishing to request Biobank support for any element of an existing ethically approved study, please consult the Secondary Biobanking Guidance Document and Application Form.

Ethics Approval & Consent

The MCRC Biobank has generic ethics approval which allows the ethics approval to be conferred to researchers who have an approved application to use samples from the MCRC Biobank as long as the research falls within the broad remit of what was written in the Biobank ethics application. The ethics currently covers a wide variety of research areas and testing.

Please note: MCRC Biobank samples are only eligible for use in cancer research projects. Any applications for non-cancer research projects will not be accepted by the MCRC Biobank.

When patients are consented for the Biobank, they have the option to consent or not for various types of research or procedures. If, for example, a patient opts out of commercial research, or genetic analysis of their samples, they may not be used for this purpose.

Where samples may be implanted into mice, the Biobank will need to consent patients using a specific animal research form.

All consent requirements should be accurately detailed in the Biobank Application Form.

Who will review applications?

Applications for use of samples for research projects will usually be scientifically reviewed by 3 reviewers consisting of both internal and external reviewers in the form of:

- 1 specialist reviewer (external to the MCRC)
- 2 clinicians or basic scientists (MCRC member)

In addition to the scientific review, applications will then be assessed by the Biobank [Access Subgroup](#).

Where there has been a delay in obtaining a review for any study, a minimum of 2 reviews may be accepted provided the Access Subgroup are satisfied.

Applications can be fast-tracked directly through the Access Subgroup in either of the following circumstances:

- It is a QC/Method Development application
- It is a full research application that has evidence of external peer review for scientific quality

How will the review take place?

Reviewers will be expected to consider each application, based on 3 distinct areas, with an overall score out of 10 to be given to the project:

- Quality
- Importance
- Impact

The MCRC Biobank scoring system and form (based on the MRC grant application scoring system) is attached as Appendix 1. Once scores and comments have been collated from the reviewers, the information will be sent out with a copy of the application and any additional comments from the reviewers to members of the MCRC Biobank Access Subgroup as part of the Rolling Programme.

Access Subgroup

The Access Subgroup will consider the project reviews, as well as any project logistics and operational issues which may impact on the Biobank's ability to deliver the samples requested in the application.

The Subgroup will also consider whether adequate funding is available to complete all aspects of the study, which should be detailed in full in the relevant section of the application form. The applicant should clearly state the source of funding and how much is available for all aspects of the work proposed. If funding is dependent on a successful Biobank application, this should be clearly stated in the proposal so that conditional approval can be offered.

The Access Subgroup will be notified of applications which receive a good or high score and are given the opportunity to raise any comments or questions by exception before approval is granted after a period of one week. For any applications which receive a low score, final Subgroup approval will be required.

Decisions on Applications

Decisions on applications will fall into one of the following categories:

- Approved with no alterations/conditions
- Approved with conditions/minor changes required
- Approval not granted – major changes and/or resubmission required
- Approval not granted – Biobank will not consider supplying samples for this type of study

The applicant will receive a letter informing them of the decision. If the proposal has not been approved, clear reasons will be given.

If the application is approved, the applicant will receive a letter informing them:

- When they can expect to receive their samples (depending on whether samples are already in the bank or whether targeted sample collection needs to take place).
- Whether there are any conditions attached for approval which must be addressed
- Whether a meeting will need to take place to discuss sample specifics
- Whether the project has been placed on a waiting list due to either resource or project capacity in that particular disease group.
- A quote for the total cost of requested samples.

Material Transfer Agreement (MTA)

Once researchers have responded to any comments raised during the review process, the MCRC Biobank can send an MTA to the applicant Principle Investigator (PI) for review and completion. The PI must return a copy of the MTA for countersignature by the MCRC Biobank Business Manager before the project can begin.

Amendments

Samples provided by the MCRC Biobank to applicants may only be used in connection with research covered under the applicant's approved application. Samples may not at any time be transferred or shared with another investigator or site which has not been detailed within the applicant's approved application. To add additional methods to the application which do not alter the aims of the study, or additional collaborators or sites for analysis of samples, an amendment will need to be submitted to the MCRC Biobank for Access Subgroup review as part of the Rolling Programme.

Once the Subgroup has made a decision, the applicants will be notified in the form of a letter with a review form including any comments raised (if applicable). The applicants will be provided with an updated MTA, if required, for review and signature.

Project Review

All projects which have a proposed endpoint surpassing 3 years will be contacted to determine whether the project needs extending via an amendment, or whether the project can be closed and remaining samples can be returned or disposed.

Publications

Researchers are expected to acknowledge the MCRC Biobank in any publications which are based on data derived from research involving samples sourced from the MCRC Biobank, by including the following in the acknowledgment section of publications: "Research samples were obtained from the Manchester Cancer Research Centre (MCRC) Biobank, UK. The MCRC Biobank holds a generic ethics approval which can confer this approval to users of banked samples via the MCRC Biobank Access Policy."

APPENDIX 1

MCRC Biobank Project Review Form

Score	Indicators
Excellent quality research	
10	Exceptional.
9	Excellent, research which is (or will be) be at the forefront internationally. Addresses very important medical or scientific questions. Likely to have a high impact on medical practice, or on the relevant scientific field.
Good quality research	
8	Good, bordering on excellent.
7	Good quality research which is internationally competitive and at the forefront of UK work. Important research which will be highly productive, and likely to have a significant impact on medical practice, if applicable.
6	Good quality research, on the border between national and international standing.
5	Good quality research which is at least nationally competitive. Addresses reasonably important questions, and will be productive. Good prospects of making some impact on medical practice, or on the relevant scientific field. Any significant concerns about the research approach can be corrected, easily.
Potentially useful study	
4	Potentially useful, bordering on good quality research.
3	Research plans which contain some good ideas or opportunities, but which are very unlikely to be productive and/or successful. Major improvements would be needed to make the proposal competitive.
Unacceptable	
2	Potentially useful in some aspects, bordering on unacceptable in others.
1	Serious scientific or ethical concerns. Should not be approved.

Project Number	
Quality Please comment	
Importance Please comment	
Impact Please comment	
Overall Score (Out of 10)	
Comments	

Signed

Date